

## Criteria For Identifying Human Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order (EO) 13944

### General criteria for the essential medicines portion of the list

1. Approved<sup>1</sup> medicines that are necessary to address immediately life-threatening medical conditions<sup>2</sup> that are encountered in US acute care medical facilities, and that are used to stabilize patients with those medical conditions so that patients can be discharged for continued outpatient care.
2. Medicines that would be used for longer-term chronic management, including those needed to cure a condition through weeks or months of outpatient treatment, are not included. While these medicines are important and medically necessary for many patients, the list is focused on addressing more immediate medical needs that are likely to occur in a public health emergency.
3. The selection of these medicines, including the dosage form and presentation (including drug-device combination products where applicable), are determined by identifying those most commonly needed for patients in US acute care medical facilities, with a focus on the dosage forms and presentations that can be used for the widest populations encountered. Specifically:
  - a. Where multiple drugs (or drug classes) treat the same condition, include the drug (or drug class) that can treat the widest population with the condition and, if possible, treat more than one condition, taking into account the needs of special patient populations that may need a particular drug in a class, for example, pediatric patients and pregnant women.
  - b. If there is more than one drug in a class as identified in (a), consider whether there are unique safety profiles that might warrant one rather than the other.
  - c. If multiple drugs in the class have different safety profiles such that it is likely that one or more drugs will be necessary to cover the entire population, consider including additional drugs.

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<sup>1</sup> Although we focused generally on approved drug and biological products, we identified a few drug products that are marketed without an approved NDA or ANDA because they met these general criteria but for the existence of an approved NDA or ANDA.

<sup>2</sup> Rare conditions are included if they are fatal within hours to days, and if this outcome is preventable with a specific medicine.

## General criteria for medicines that are included in the medical countermeasures (MCMs) portion of the list

1. Consistent with the definition of “Medical Countermeasures” set forth in Section 7(j) of the EO, the selection of MCMs was primarily based on the statutory definitions of “Qualified Countermeasure”, “Qualified Pandemic or Epidemic Product”, and “Security Countermeasure” (below). This selection included those agents we anticipate needing to respond to future pandemics, epidemics, and chemical, biological, and radiological/nuclear (CBRN) threats.
  - a. Qualified Countermeasures - CDER and CBER considered all approved products that are included in the Strategic National Stockpile.
  - b. Qualified Pandemic or Epidemic Products - CDER and CBER included approved vaccines and antiviral drugs to treat influenza.
  - c. Security Countermeasures - CDER and CBER considered all approved drug products associated with the prevention, mitigation or treatment of CBRN (Chemical, Biological, and Radiological/Nuclear) threats.
2. The selection of medicines, including dosage forms and presentations (including drug-device combination products), was informed by available lists of MCMs developed by FDA and other Agencies. Because the selection also aligns with national MCM stockpile planning, certain products to treat thermal burns, mechanical trauma, and radiation injuries are also included.
3. MCMs are limited to medicines that are approved or otherwise legally marketed in the US. This category may in some cases include medicines that are approved or otherwise legally marketed, but for which the MCM use is not included in the product’s labeling.
4. In general, a medicine that meets one of the three statutory definitions described above is included on the list and be determined to be “medically necessary ...” as set forth in the EO. However, medicines that meet the definition of “qualified pandemic or epidemic product” but are only available pursuant to an IND or EUA will generally not be deemed to be “medically necessary ...” and have been excluded from the list. We will add such medicines to the list once they are approved. Further, for approved medicines for which the MCM use is not included in the product’s labeling, the product will not be considered “medically necessary ...” and will not be included on the list if FDA has information to suggest they are unsafe or ineffective for use as an MCM (e.g. those for which we’ve determined an EUA is not appropriate).

## General criteria for the critical inputs portion of the list

Section 3(c) of the EO requires FDA to, among other things, identify a list of “Essential Medicines, Medical Countermeasures, and their Critical Inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms.” Under section 7 of the EO, Critical Inputs for Essential Medicines and Medical Countermeasures include:

- APIs
- Starting materials that the Commissioner determines satisfy the criteria stated in the EO’s definition of “API Starting Material,” and

- Other ingredients of drugs that the Commissioner determines satisfy the criteria stated in the EO’s definition of “Critical Inputs.”

Guided by the purpose and language of the EO and the discretion afforded to the Commissioner in determining which starting materials and other ingredients to identify as medically necessary Critical Inputs, FDA has developed the following general criteria for identifying Critical Inputs for Essential Medicines and Medical Countermeasures:

1. All APIs
2. All active ingredients or starting materials for biological and natural source products (e.g. cell lines, master cell bank, human plasma, crude heparin). FDA has not identified starting materials for small molecule APIs that meet the criteria of the EO.
3. Ingredients or constituent parts that possess unique attributes essential to the approved uses of the product, which may include:
  - a. Excipients and other ingredients that have unique properties that are directly related to one or more of the critical uses of the drug or biologic.
  - b. Device constituent parts of Essential Medicines or Medical Countermeasures that are single-entity drug-device or biological product-device combination products approved under a single BLA, NDA, or ANDA.

## Criteria for identifying medical device MCMs and critical inputs for the list described in Section 3(c) of Executive Order 13944

### Medical countermeasure (MCM) inclusion criteria

A device [as defined in section 201(h) of the FD&C Act] qualifies as an MCM, as defined in Section 7(j) of the EO, if the device meets the following criteria:

1. Fits within the definition of one of four elements of the MCM definition provided in the EO:
  - a. ‘qualified countermeasure’ (as defined in 42 USC 247d–6a(a)(2)(A);
  - b. ‘qualified pandemic or epidemic product’ (as defined in 42 USC 247d–6d(i)(7));
  - c. ‘security countermeasure’ (as defined in 42 USC 247d–6b(c)(1)(B)); or
  - d. ‘personal protective equipment’ (PPE, as described in 29 CFR part 1910);
2. Is always medically necessary to have available in adequate supply;
3. Is not able to be substituted by another device on the list; and
4. Meets one or more of the following:
  - a. Diagnostic testing and supplies generally applicable to PCR testing to enable rapid test development and processing;

- b. PPE needed to protect healthcare workers from airborne, blood-borne, waterborne, chemical, biological, radiological or nuclear events;
- c. Devices that are not permanently implanted that are intended to provide acute mechanical support in treating an acute event or condition in a healthcare setting for vital physiologic functions and are not intended solely for the treatment of chronic conditions;
  - i. Devices that provide adequate vital signs monitoring in a healthcare setting to enable the use of the mechanical support MCM devices;
- d. Devices used for the delivery of a vaccine that are intended to prevent or mitigate the spread of an epidemic or pandemic; or
- e. Devices used for the acute management of injury or illness caused by chemical, biological, radiological or nuclear events.

### Critical input inclusion criteria

A device component [as defined 21 CFR 820.3(c)] qualifies as a CI, as defined in Section 7(d) of the EO, on the basis that it is:

1. A component of a medical device identified on the list;
2. Always medically necessary to have available in adequate supply;
3. Critical to assessing the safety and effectiveness of a device identified on the list, as established by meeting the following criteria:
  - a. Be critical for the use/manufacture of a device identified on the list;
  - b. Reasonable substitutes are not easily available:
    - i. Inputs are so unique that there are no or limited substitutes; or
    - ii. Inputs are widely used in multiple devices identified on the list; and
  - c. Substitutions (or modifications or omissions) generally would require a reassessment of safety and effectiveness of the identified device;
4. Expected to be part of most devices identified on the list for a specific device type (i.e., not a unique component specific to a proprietary device); and
5. Not components for which their identification could potentially disclose confidential commercial information and trade secret information.

### Additional information

For additional information, please see the FDA web page, Executive Order 13944 List of Essential Medicines, MCMs, & Critical Inputs, at: <https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs>